

**Notice of Allowability**

Application No.

10/750,475

Applicant(s)

ALAVATTAM ET AL.

Examiner

Robert A. Wax

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed December 27, 2005.
2. ☒ The allowed claim(s) is/are 1, 3-5, 7-9, 11, 21 and 23-40.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  
\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.  
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.  
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>01302006</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                               | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed January 30, 2006 has been considered. Please see the attached initialed PTO-1449s. The references that were lined through were already cited in a previous Office action.

### **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Klaus Wiesmann on January 23, 2006.

The application has been amended as follows:

Rewrite claim 4:

4. (Amended) The controlled release formulation according to claim 1, wherein the biodegradable polymer is a hydrophobic bioabsorbable polymer.

In claim 29, delete, "form" and substitute therefor - -from- -;

In claim 30, delete, "polysaccharides" and substitute therefor - -controlled release formulation- -;

Rewrite claim 32:

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32. (Amended) The controlled release formulation according to claim 11, wherein the biodegradable polymer is a hydrophobic bioabsorbable polymer.

Amend claim 33 as follows: delete, "a group" and substitute therefor - -the group consisting of- -;

Amend claim 34 as follows: delete, "copolymers" and substitute therefor - - -copolymer- -;

Add new claim 38:

38. (New) The controlled release formulation according to claim 4, wherein the hydrophobic bioabsorbable polymer is selected from the group consisting of polyglycolide, polylactide (D, L, DL), polydioxanones, polyester carbonates, polyhydroxyalkanoates, polycaprolactone (polylactones), polyethylene glycol, and copolymers thereof.

Add new claim 39:

39. (New) The controlled release formulation according to claim 38, wherein the hydrophobic bioabsorbable polymer is selected from the group consisting of polyglycolide or polylactide, or a copolymer or polyglycolide-caprolactone of polyglycolide and polylactide, polylactide-polycaprolactone.

Add new claim 40:

40. (New) The controlled release formulation according to claim 32, wherein the hydrophobic bioabsorbable polymer is selected from the group consisting of polyglycolide, polylactide (D, L, DL), polydioxanones, polyester carbonates, polyhydroxyalkanoates, polycaprolactone (polylactones), polyethylene glycol, and copolymers thereof.

3. The following is an examiner's statement of reasons for allowance: The prior art neither teaches nor suggests coating the protein/polysaccharide microparticles with surfactant prior to encapsulation.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax  
Primary Examiner  
Art Unit 1653

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